Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	3 (3.5)	3 (4.6)	3 (7.0)
BREAST MASS	5 (5.8)	5 (7.7)	5 (11.6)
BREAST PAIN	0 (0.0)	0 (0.0)	0 (0.0)
CAPSULAR CONSTRACTURE III/IV	24 (27.9)	17 (26.2)	13 (30 2)
DELAYED WOUND HEALING	4 (4.7)	3 (4.6)	3 (7.0)
EXTRUSION	3 (3.5)	3 (4.6)	3 (7 0)
HEMATOMA	5 (5.8)	4 (6.2)	4 (9.3)
HYPERTROPHIC SCARRING	4 (4.7)	4 (6.2)	2 (4.7)
IMPLANT MALPOSITION/DISPLACEMENT	3 (3.5)	3 (4.6)	2 (4.7)
INFECTION	1 (1.2)	1 (1.5)	1 (2.3)
IRRITATION/INFLAMMATION	1 (1.2)	1 (1.5)	1 (2.3)
NIPPLE RELATED (UNPLANNED)	2 (2.3)	2 (3.1)	1 (2.3)
PATIENT REQUEST	12 (14.0)	12 (18.5)	7 (16.3)
PTOSIS	2 (2.3)	2 (3.1)	1 (2.3)
SEROMA	1 (1.2)	1 (1.5)	1 (2.3)
WRINKLING	4 (4.7)	4 (6.2)	2 (4.7)
OTHER	12 (14 0)	9 (13.8)	6 (14 0)
BREAST / SKIN LESIONS	3 (3.5)	2 (3.1)	1 (2.3)
EXTRA SKIN BUMP	0 (0.0)	0 (0.0)	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	0 (0.0)	0 (0.0)	0 (0.0)
GRANULOMA	1 (1.2)	1 (1.5)	1 (2.3)
LACK OF PROJECTION	0 (0.0)	0 (0.0)	0 (0.0)
MUSCLE SPASM	0 (0.0)	0 (0.0)	0 (0.0)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
PATIENT DISSATISFIED WITH APPEARANCE	2 (2.3)	2 (3.1)	1 (2.3)
POCKET TEAR	1 (1.2)	1 (1.5)	1 (2.3)
RECURRENT BREAST CANCER	1 (1.2)	1 (1.5)	1 (2.3)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)	0 (0.0)	0 (0.0)
SUTURE REACTION	0 (0.0)	0 (0.0)	0 (0.0)
SYMMASTIA	4 (4.7)	2 (3.1)	1 (2.3)
TEAR IN CAPSULE	0 (0.0)	0 (0.0)	0 (0.0)
TIGHT BUNILLI SUTURE	0 (0.0)	0 (0.0)	0 (0.0)
MISSING	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL ASSESSED WITH REOPERATION	86 (100.0)	65 (100.0)	43 (100.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No of Implants n(%)	No. of Patients n(%)
ASYMMETRY	3 (3.0)	3 (3.8)	3 (5.9)
BREAST MASS	6 (6.0)	6 (7.7)	6 (11.8)
BREAST PAIN	0 (0.0)	0 (0.0)	0 (0.0)
CAPSULAR CONSTRACTURE III/IV	28 (28.0)	21 (26.9)	16 (31.4)
DELAYED WOUND HEALING	4 (4.0)	3 (3.8)	3 (5.9)
EXTRUSION	3 (3.0)	3 (3.8)	3 (5.9)
HEMATOMA	5 (5.0)	4 (5.1)	4 (7.8)
HYPERTROPHIC SCARRING	5 (5.0)	5 (6.4)	3 (5.9)
IMPLANT MALPOSITION/DISPLACEMENT	3 (3.0)	3 (3.8)	2 (3.9)
INFECTION	1 (1.0)	1 (1.3)	1 (2.0)
IRRITATION/INFLAMMATION	1 (1.0)	1 (1.3)	1 (2.0)
NECROSIS	0 (0.0)	0 (0.0)	0 (0.0)
NIPPLE RELATED (UNPLANNED)	2 (2.0)	2 (2.6)	1 (2.0)
PATIENT REQUEST	14 (14.0)	14 (17.9)	8 (15.7)
PTOSIS	4 (4.0)	4 (5.1)	2 (3.9)
SEROMA	1 (1.0)	1 (1.3)	1 (2.0)
WRINKLING	4 (4.0)	4 (5.1)	2 (3.9)
OTHER	15 (15.0)	12 (15.4)	9 (17.6)
ABNORMAL MAMMOGRAM	1 (1.0)	1 (1.3)	1 (2.0)
BREAST / SKIN LESIONS	3 (3.0)	2 (2.6)	1 (2.0)
EXTRA SKIN BUMP	0 (0.0)	0 (0.0)	0 (0.0)
FALSE POSITIVE MRI FOR RUPTURE	1 (1.0)	1 (1.3)	1 (2.0)
GRANULOMA	1 (1.0)	1 (1.3)	1 (2.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2. Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
REVISION PATIENTS

Time Period. 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
LACK OF PROJECTION	0 (0.0)	0 (0.0)	0 (0.0)
MUSCLE SPASM	0 (0.0)	0 (0.0)	0 (0.0)
PATIENT DISSATISFIED WITH APPEARANCE	2 (2.0)	2 (2.6)	1 (2.0)
POCKET TEAR	1 (1.0)	1 (1.3)	1 (2.0)
RECURRENT BREAST CANCER	1 (1.0)	1 (1.3)	1 (2.0)
RIGHT EXPLANTED SO LEFT DONE ALSO	0 (0.0)	0 (0.0)	0 (0.0)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	0 (0.0)	0 (0.0)	0 (0.0)
SUSPECTED RUPTURE	1 (1.0)	1 (1.3)	1 (2.0)
SUTURE REACTION	0 (0.0)	0 (0.0)	0 (0.0)
SYMMASTIA	4 (4.0)	2 (2.6)	1 (2.0)
TEAR IN CAPSULE	0 (0.0)	0 (0.0)	0 (0.0)
TIGHT BUNILLI SUTURE	0 (0.0)	0 (0.0)	0 (0.0)
TOO LARGE	0 (0.0)	0 (0.0)	0 (0.0)
MISSING	1 (1.0)	1 (1.3)	1 (2.0)
TOTAL ASSESSED WITH REOPERATION	100 (100 0)	78 (100.0)	51 (100.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	21 (10.5)	21 (11 8)	18 (13.5)
BREAST MASS	11 (5.5)	10 (5.6)	9 (6.8)
BREAST PAIN	1 (0.5)	1 (0.6)	1 (0.8)
CAPSULAR CONSTRACTURE III/IV	49 (24.5)	43 (24.2)	31 (23.3)
DELAYED WOUND HEALING	5 (2.5)	4 (2.2)	4 (3.0)
EXTRUSION	6 (3.0)	6 (3.4)	6 (4.5)
HEMATOMA	15 (7.5)	13 (7.3)	13 (9.8)
HYPERTROPHIC SCARRING	6 (3.0)	6 (3.4)	4 (3.0)
IMPLANT MALPOSITION/DISPLACEMENT	10 (5.0)	10 (5.6)	9 (6.8)
INFECTION	7 (3.5)	7 (3.9)	7 (5.3)
IRRITATION/INFLAMMATION	1 (0.5)	1 (0.6)	1 (0.8)
NIPPLE RELATED (UNPLANNED)	4 (2.0)	4 (2.2)	3 (2.3)
PATIENT REQUEST	34 (17.0)	34 (19.1)	19 (14.3)
PTOSIS	3 (1.5)	3 (1.7)	2 (1.5)
SEROMA	3 (1.5)	3 (1.7)	3 (2.3)
WRINKLING	3 (1.5)	3 (1.7)	2 (1.5)
OTHER	19 (9.5)	16 (9.0)	13 (9.8)
BREAST / SKIN LESIONS	3 (1.5)	3 (1.7)	2 (1.5)
EXTRA SKIN BUMP	1 (0.5)	1 (0.6)	1 (0.8)
GRANULOMA	1 (0.5)	1 (0.6)	1 (0.8)
MUSCLE SPASM	1 (0.5)	1 (0.6)	1 (0.8)
POCKET TEAR	1 (0.5)	1 (0.6)	1 (0.8)
RECURRENT BREAST CANCER	3 (1.5)	2 (1.1)	2 (1.5)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2. Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 12 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No of Patients n(%)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (1.0)	2 (1.1)	1 (0.8)
SUTURE REACTION	1 (0.5)	1 (0.6)	1 (0.8)
SYMMASTIA	4 (2.0)	2 (1.1)	1 (0.8)
TEAR IN CAPSULE	1 (0.5)	1 (0.6)	1 (0.8)
TIGHT BUNILLI SUTURE	1 (0.5)	1 (0.6)	1 (0.8)
MISSING	2 (1.0)	2 (1.1)	2 (1.5)
TOTAL ASSESSED WITH REOPERATION	200 (100.0)	178 (100.0)	133 (100.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	28 (9.8)	27 (11.1)	23 (13.2)
BREAST MASS	16 (5.6)	15 (6.1)	14 (8.0)
BREAST PAIN	3 (1.0)	3 (1.2)	2 (1.1)
CAPSULAR CONSTRACTURE III/IV	70 (24.5)	60 (24.6)	45 (25.9)
DELAYED WOUND HEALING	5 (1.7)	4 (1.6)	4 (2.3)
EXTRUSION	6 (2.1)	6 (2.5)	6 (3.4)
HEMATOMA	17 (5.9)	15 (6.1)	15 (8.6)
HYPERTROPHIC SCARRING	19 (6.6)	19 (7.8)	12 (6.9)
IMPLANT MALPOSITION/DISPLACEMENT	17 (5.9)	17 (7.0)	13 (7.5)
INFECTION	8 (2.8)	8 (3.3)	8 (4.6)
IRRITATION/INFLAMMATION	1 (0.3)	1 (0.4)	1 (0.6)
NIPPLE RELATED (UNPLANNED)	4 (1.4)	4 (1.6)	3 (1.7)
PATIENT REQUEST	49 (17.1)	49 (20.1)	28 (16.1)
PTOSIS	7 (2.4)	7 (2.9)	4 (2.3)
SEROMA	3 (1.0)	3 (1.2)	3 (1.7)
WRINKLING	7 (2.4)	7 (2.9)	4 (2.3)
OTHER	24 (8.4)	20 (8.2)	16 (9.2)
BREAST / SKIN LESIONS	4 (1.4)	3 (1.2)	2 (1.1)
EXTRA SKIN BUMP	1 (0.3)	1 (0.4)	1 (0.6)
FALSE POSITIVE MRI FOR RUPTURE	1 (0.3)	1 (0.4)	1 (0.6)
GRANULOMA	1 (0.3)	1 (0.4)	1 (0.6)
LACK OF PROJECTION	1 (0.3)	1 (0.4)	1 (0.6)
MUSCLE SPASM	1 (0.3)	1 (0.4)	1 (0.6)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 24 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
PATIENT DISSATISFIED WITH APPEARANCE	2 (0.7)	2 (0.8)	1 (0 6)
POCKET TEAR	1 (0.3)	1 (0.4)	1 (0.6)
RECURRENT BREAST CANCER	3 (1.0)	2 (0.8)	2 (1.1)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (0.7)	2 (0.8)	1 (0.6)
SUTURE REACTION	1 (0.3)	1 (0 4)	1 (0.6)
SYMMASTIA	4 (1.4)	2 (0.8)	1 (0.6)
TEAR IN CAPSULE	1 (0 3)	1 (0.4)	1 (0 6)
TIGHT BUNILLI SUTURE	1 (0.3)	1 (0.4)	1 (0.6)
MISSING	2 (0.7)	2 (0.8)	2 (1.1)
TOTAL ASSESSED WITH REOPERATION	286 (100.0)	244 (100.0)	174 (100.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	28 (8.5)	27 (9.8)	23 (11.9)
BREAST MASS	19 (5.8)	18 (6.5)	17 (8.8)
BREAST PAIN	3 (0.9)	3 (1.1)	2 (1.0)
CAPSULAR CONSTRACTURE III/IV	81 (24.6)	68 (24.7)	52 (26.8)
DELAYED WOUND HEALING	5 (1.5)	4 (1.5)	4 (2.1)
EXTRUSION	6 (1.8)	6 (2.2)	6 (3.1)
HEMATOMA	18 (5.5)	16 (5.8)	16 (8.2)
HYPERTROPHIC SCARRING	23 (7.0)	23 (8.4)	15 (7.7)
IMPLANT MALPOSITION/DISPLACEMENT	17 (5.2)	17 (6.2)	13 (6.7)
INFECTION	8 (2.4)	8 (2.9)	8 (4.1)
IRRITATION/INFLAMMATION	1 (0.3)	1 (0.4)	1 (0.5)
NECROSIS	2 (0.6)	2 (0.7)	1 (0.5)
NIPPLE RELATED (UNPLANNED)	4 (1.2)	4 (1.5)	3 (1.5)
PATIENT REQUEST	58 (17.6)	58 (21.1)	33 (17.0)
PTOSIS	13 (4.0)	12 (4.4)	7 (3.6)
SEROMA	3 (0.9)	3 (1.1)	3 (1.5)
WRINKLING	7 (2.1)	7 (2.5)	4 (2.1)
OTHER	30 (9.1)	26 (9.5)	21 (10.8)
ABNORMAL MAMMOGRAM	1 (0.3)	1 (0.4)	1 (0.5)
BREAST / SKIN LESIONS	4 (1.2)	3 (1.1)	2 (1.0)
EXTRA SKIN BUMP	1 (0.3)	1 (0.4)	1 (0.5)
FALSE POSITIVE MRI FOR RUPTURE	2 (0.6)	2 (0.7)	2 (1.0)
GRANULOMA	1 (0.3)	1 (0.4)	1 (0.5)

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Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 9.2

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION - FDA Item 11
OVERALL PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
LACK OF PROJECTION	1 (0.3)	1 (0.4)	1 (0.5)
MUSCLE SPASM	1 (0.3)	1 (0.4)	1 (0.5)
PATIENT DISSATISFIED WITH APPEARANCE	2 (0.6)	2 (0.7)	1 (0.5)
POCKET TEAR	1 (0.3)	1 (0.4)	1 (0.5)
RECURRENT BREAST CANCER	3 (0.9)	2 (0.7)	2 (1.0)
RIGHT EXPLANTED SO LEFT DONE ALSO	1 (0 3)	1 (0.4)	1 (0.5)
STAGED RECONSTRUCTION AND LEFT MASS, CHEST WALL	2 (0.6)	2 (0.7)	1 (0.5)
SUSPECTED RUPTURE	1 (0.3)	1 (0.4)	1 (0.5)
SUTURE REACTION	1 (0.3)	1 (0.4)	1 (0.5)
SYMMASTIA	4 (1.2)	2 (0.7)	1 (0.5)
TEAR IN CAPSULE	1 (0.3)	1 (0.4)	1 (0.5)
TIGHT BUNILLI SUTURE	1 (0.3)	1 (0.4)	1 (0.5)
TOO LARGE	2 (0.6)	2 (0.7)	1 (0.5)
MISSING	3 (0.9)	3 (1.1)	3 (1.5)
TOTAL ASSESSED WITH REOPERATION	329 (100.0)	275 (100.0)	194 (100.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Only the primary reason was to be recorded by the physician on a per-operation basis. Patients having multiple operations will therefore be counted under multiple primary reasons. Consequently, percentages calculated on the implant and patient level may exceed 100%.
Note 3: Percentages are based upon Total Assessed with Reoperation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.1

REOPERATIVE REPORT: IMPLANT INFORMATION

Time Period: 0 - 12 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Variable	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)
Explantation								
Right		3 (27.3)		8 (40.0)		5 (41.7)		16 (37.2)
Left		0 (0.0)		6 (30.0)		1 (8.3)		7 (16.3)
Both		8 (72.7)		6 (30.0)		6 (50.0)		20 (46.5)
Total		11 (100.0)		20 (100.0)		12 (100.0)		43 (100.0)
Implant to be Returned for Analysis								
No	10 (52.6)		10 (38.5)		2 (11.1)		22 (34.9)	
Yes	9 (47.4)		14 (53.8)		16 (88.9)		39 (61.9)	
Missing	0 (0.0)		2 (7.7)		0 (0.0)		2 (3.2)	
Total	19 (100.0)		26 (100.0)		18 (100.0)		63 (100.0)	
New Study Implant Used								
Right		2 (22.2)		4 (30.8)		3 (37.5)		9 (30.0)
Left		1 (11.1)		5 (38.5)		1 (12.5)		7 (23.3)
Both		6 (66.7)		4 (30.8)		4 (50.0)		14 (46.7)
Total		9 (100.0)		13 (100.0)		8 (100.0)		30 (100.0)

Note 1. Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Percentages are based upon number of implants or patients, as applicable, having an explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
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Table 9.3.1

REOPERATIVE REPORT. IMPLANT INFORMATION

Time Period: 0 - 24 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Variable	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)
Explantation								
Right		3 (16.7)		12 (41.4)		8 (42.1)		23 (34.8)
Left		3 (16.7)		9 (31 0)		1 (5.3)		13 (19.7)
Both		12 (66.7)		8 (27.6)		10 (52.6)		30 (45.5)
Total		18 (100.0)		29 (100.0)		19 (100.0)		66 (100.0)
Implant to be Returned for Analysis								
No	14 (46.7)		16 (43.2)		2 (6.9)		32 (33.3)	
Yes	16 (53.3)		19 (51.4)		25 (86.2)		60 (62.5)	
Missing	0 (0.0)		2 (5.4)		2 (6.9)		4 (4.2)	
Total	30 (100.0)		37 (100.0)		29 (100.0)		96 (100.0)	
New Study Implant Used								
Right		2 (15.4)		5 (27.8)		5 (41.7)		12 (27.9)
Left		4 (30.8)		8 (44.4)		1 (8.3)		13 (30.2)
Both		7 (53.8)		5 (27.8)		6 (50.0)		18 (41.9)
Total		13 (100.0)		18 (100.0)		12 (100.0)		43 (100.0)

Note 1: Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Percentages are based upon number of implants or patients, as applicable, having an explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9 3.1

REOPERATIVE REPORT: IMPLANT INFORMATION

Time Period: 0 - 36 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Variable	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)	No. of Breasts n(%)	No. of Patients (a) n(%)
Explantation								
Right		3 (12.5)		12 (38.7)		8 (33.3)		23 (29.1)
Left		4 (16.7)		9 (29.0)		3 (12.5)		16 (20.3)
Both		17 (70.8)		10 (32.3)		13 (54.2)		40 (50.6)
Total		24 (100.0)		31 (100.0)		24 (100.0)		79 (100.0)
Implant to be Returned for Analysis								
No	14 (34.1)		16 (39.0)		5 (13.5)		35 (29.4)	
Yes	27 (65.9)		23 (56.1)		30 (81.1)		80 (67.2)	
Missing	0 (0.0)		2 (4.9)		2 (5.4)		4 (3.4)	
Total	41 (100.0)		41 (100.0)		37 (100.0)		119 (100.0)	
New Study Implant Used								
Right		2 (13.3)		5 (27.8)		5 (35.7)		12 (25.5)
Left		4 (26.7)		8 (44.4)		2 (14.3)		14 (29.8)
Both		9 (60.0)		5 (27.8)		7 (50.0)		21 (44.7)
Total		15 (100.0)		18 (100.0)		14 (100.0)		47 (100.0)

Note 1 Excludes planned second stage surgeries and reoperations for which the only reason for reoperation was staged reconstruction.
Note 2. Percentages are based upon number of implants or patients, as applicable, having an explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.2

REOPERATIVE REPORT: REASON FOR EXPLANT / REIMPLANT WITH NEW STUDY DEVICE - FDA Item 12

Time Period: 0 - 12 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Explant/Reimplant	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
SAME AS PRIMARY REASON FOR SECONDARY PROCEDURE	13 (92.9)	7 (87.5)	15 (88.2)	11 (84.6)	12 (100.0)	8 (100.0)	40 (93.0)	26 (89.7)
ASYMMETRY	0 (0.0)	0 (0.0)	7 (41.2)	6 (46.2)	0 (0.0)	0 (0.0)	7 (16.3)	6 (20.7)
CAPSULAR CONSTRACTURE III/IV	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (33.3)	2 (25.0)	4 (9.3)	2 (6.9)
EXTRUSION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (12.5)	1 (2.3)	1 (3.4)
HEMATOMA	0 (0.0)	0 (0.0)	1 (5.9)	1 (7.7)	0 (0.0)	0 (0.0)	1 (2.3)	1 (3.4)
HYPERTROPHIC SCARRING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (12.5)	1 (2.3)	1 (3.4)
IMPLANT MALPOSITION/DISPLACEMENT	0 (0.0)	0 (0.0)	1 (5.9)	1 (7.7)	0 (0.0)	0 (0.0)	1 (2 3)	1 (3.4)
PATIENT REQUEST	13 (92.9)	7 (87.5)	6 (35.3)	4 (30.8)	3 (25.0)	2 (25.0)	22 (51.2)	13 (44.8)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (25.0)	2 (25.0)	3 (7.0)	2 (6.9)
Pocket Tear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)	1 (12.5)	1 (2.3)	1 (3.4)
Symmastia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (16.7)	1 (12.5)	2 (4.7)	1 (3.4)
POCKET SIZE CHANGED	1 (7.1)	1 (12.5)	1 (5.9)	1 (7.7)	0 (0.0)	0 (0.0)	2 (4.7)	2 (6.9)
OTHER	0 (0.0)	0 (0.0)	1 (5.9)	1 (7.7)	0 (0.0)	0 (0.0)	1 (2.3)	1 (3.4)
ABNORMAL CONTRACTURE	0 (0.0)	0 (0.0)	1 (5.9)	1 (7.7)	0 (0.0)	0 (0.0)	1 (2.3)	1 (3.4)
TOTAL ASSESSED WITH EXPLANT/REIMPLANT	14 (100.0)	8 (100.0)	17 (100.0)	13 (100.0)	12 (100.0)	8 (100.0)	43 (100.0)	29 (100.0)

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Note 1: Excludes reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Percentages are based upon number of implants or patients, as applicable, having an explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.2

REOPERATIVE REPORT: REASON FOR EXPLANT / REIMPLANT WITH NEW STUDY DEVICE - FDA Item 12

Time Period: 0 - 24 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Explant/Reimplant	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
SAME AS PRIMARY REASON FOR SECONDARY PROCEDURE	15 (75.0)	9 (69.2)	20 (87.0)	15 (83.3)	18 (100.0)	12 (100.0)	53 (86.9)	36 (83.7)
ASYMMETRY	0 (0.0)	0 (0.0)	8 (34.8)	7 (38.9)	2 (11.1)	2 (16.7)	10 (16.4)	9 (20.9)
CAPSULAR CONSTRACTURE III/IV	2 (10.0)	2 (15.4)	2 (8.7)	2 (11.1)	5 (27.8)	3 (25.0)	9 (14.8)	7 (16.3)
EXTRUSION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (8 3)	1 (1.6)	1 (2.3)
HEMATOMA	0 (0.0)	0 (0.0)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.6)	1 (2.3)
HYPERTROPHIC SCARRING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (8.3)	1 (1.6)	1 (2.3)
IMPLANT MALPOSITION/DISPLACEMENT	0 (0.0)	0 (0.0)	3 (13.0)	2 (11.1)	0 (0.0)	0 (0.0)	3 (4.9)	2 (4.7)
PATIENT REQUEST	13 (65.0)	7 (53.8)	6 (26.1)	4 (22.2)	6 (33.3)	4 (33.3)	25 (41.0)	15 (34.9)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)	0 (0 0)	3 (16.7)	2 (16.7)	3 (4.9)	2 (4.7)
Pocket Tear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (8.3)	1 (1.6)	1 (2.3)
Symmastia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.1)	1 (8.3)	2 (3.3)	1 (2.3)
POCKET SIZE CHANGED	2 (10.0)	2 (15.4)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	3 (4.9)	3 (7.0)
OTHER	3 (15.0)	2 (15.4)	2 (8.7)	2 (11.1)	0 (0.0)	0 (0.0)	5 (8.2)	4 (9.3)
ABNORMAL CONTRACTURE	0 (0.0)	0 (0.0)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.6)	1 (2.3)
INFLAMMATORY REACTION / SEROMA	1 (5.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (2.3)
LARGER SIZE	0 (0.0)	0 (0.0)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (1 6)	1 (2.3)
WANTED TO BE LARGER	2 (10.0)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.3)	1 (2.3)

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Note 1: Excludes reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Percentages are based upon number of implants or patients, as applicable, having an explantation.

Table 9.3.2

REOPERATIVE REPORT: REASON FOR EXPLANT / REIMPLANT WITH NEW STUDY DEVICE - FDA Item 12

Time Period. 0 - 24 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Explant/Reimplant	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
TOTAL ASSESSED WITH EXPLANT/REIMPLANT	20 (100.0)	13 (100.0)	23 (100.0)	18 (100.0)	18 (100.0)	12 (100.0)	61 (100.0)	43 (100.0)

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Creation Date, Time: 24AUG04 09:04

Note 1: Excludes reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Percentages are based upon number of implants or patients, as applicable, having an explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.2

REOPERATIVE REPORT. REASON FOR EXPLANT / REIMPLANT WITH NEW STUDY DEVICE - FDA Item 12

Time Period: 0 - 36 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Explant/Reimplant	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
SAME AS PRIMARY REASON FOR SECONDARY PROCEDURE	19 (79.2)	11 (73.3)	20 (87.0)	15 (83 3)	21 (100.0)	14 (100.0)	60 (88.2)	40 (85.1)
ASYMMETRY	0 (0.0)	0 (0.0)	8 (34.8)	7 (38.9)	2 (9.5)	2 (14.3)	10 (14.7)	9 (19.1)
CAPSULAR CONSTRACTURE III/IV	2 (8.3)	2 (13.3)	2 (8.7)	2 (11.1)	7 (33.3)	5 (35.7)	11 (16.2)	9 (19.1)
EXTRUSION	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)	1 (7.1)	1 (1.5)	1 (2.1)
HEMATOMA	0 (0.0)	0 (0.0)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.1)
HYPERTROPHIC SCARRING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)	1 (7.1)	1 (1.5)	1 (2.1)
IMPLANT MALPOSITION/DISPLACEMENT	0 (0.0)	0 (0.0)	3 (13.0)	2 (11.1)	0 (0.0)	0 (0.0)	3 (4.4)	2 (4.3)
PATIENT REQUEST	17 (70.8)	9 (60.0)	6 (26.1)	4 (22.2)	6 (28.6)	4 (28.6)	29 (42.6)	17 (36.2)
OTHER	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (19.0)	3 (21.4)	4 (5.9)	3 (6.4)
Pocket Tear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)	1 (7.1)	1 (1.5)	1 (2.1)
Suspected Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.8)	1 (7.1)	1 (1.5)	1 (2.1)
Symmastia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (9.5)	1 (7.1)	2 (2 9)	1 (2.1)
POCKET SIZE CHANGED	2 (8.3)	2 (13.3)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	3 (4.4)	3 (6.4)
OTHER	3 (12.5)	2 (13.3)	2 (8.7)	2 (11.1)	0 (0.0)	0 (0.0)	5 (7.4)	4 (8.5)
ABNORMAL CONTRACTURE	0 (0.0)	0 (0.0)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.1)
INFLAMMATORY REACTION / SEROMA	1 (4.2)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.1)
LARGER SIZE	0 (0.0)	0 (0.0)	1 (4.3)	1 (5.6)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.1)
WANTED TO BE LARGER	2 (8.3)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	1 (2.1)

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Note 1: Excludes reoperations for which the only reason for reoperation was staged reconstruction.
Note 2. Percentages are based upon number of implants or patients, as applicable, having an explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.2

REOPERATIVE REPORT: REASON FOR EXPLANT / REIMPLANT WITH NEW STUDY DEVICE - FDA Item 12

Time Period: 0 - 36 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Explant/Reimplant	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
TOTAL ASSESSED WITH EXPLANT/REIMPLANT	24 (100.0)	15 (100.0)	23 (100.0)	18 (100.0)	21 (100.0)	14 (100.0)	68 (100.0)	47 (100.0)

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Note 1: Excludes reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Percentages are based upon number of implants or patients, as applicable, having an explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.3

REOPERATIVE REPORT: REASON FOR IMPLANT REMOVAL - FDA Item 12

Time Period. 0 - 12 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Removal (1,2)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
AT LEAST ONE EXPLANTATION	22 (100 0)	13 (100.0)	26 (100.0)	20 (100.0)	18 (100.0)	12 (100.0)	66 (100.0)	45 (100.0)
ASYMMETRY	0 (0.0)	0 (0.0)	8 (30.8)	7 (35.0)	1 (5.6)	1 (8 3)	9 (13.6)	8 (17.8)
CAPSULAR CONSTRACTURE III/IV	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (33.3)	3 (25.0)	6 (9.1)	3 (6.7)
EXTRUSION	0 (0.0)	0 (0.0)	2 (7.7)	2 (10.0)	2 (11.1)	2 (16.7)	4 (6.1)	4 (8.9)
HEMATOMA	0 (0.0)	0 (0.0)	1 (3.8)	1 (5.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.2)
HYPERTROPHIC SCARRING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (8.3)	1 (1.5)	1 (2.2)
INFECTION	2 (9.1)	2 (15.4)	2 (7.7)	2 (10.0)	0 (0.0)	0 (0.0)	4 (6.1)	4 (8.9)
IMPLANT MALPOSITION/DISPLACEMENT	0 (0.0)	0 (0.0)	1 (3.8)	1 (5.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.2)
PATIENT REQUEST	15 (68.2)	8 (61.5)	10 (38.5)	6 (30.0)	5 (27.8)	3 (25.0)	30 (45.5)	17 (37.8)
WRINKLING	1 (4.5)	1 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.2)
OTHER	0 (0.0)	0 (0.0)	2 (7.7)	2 (10.0)	3 (16.7)	2 (16.7)	5 (7.6)	4 (8.9)
Muscle Spasm	0 (0.0)	0 (0.0)	1 (3.8)	1 (5.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.2)
Pocket Tear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (8.3)	1 (1.5)	1 (2.2)
Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (3.8)	1 (5.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.2)
Symmastia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.1)	1 (8.3)	2 (3.0)	1 (2.2)
MISSING	4 (18.2)	2 (15.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (6.1)	2 (4.4)

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Note 1: Includes all implant removals with or without replacement reported up to 12 months post-implant surgery.
Note 2: Excludes reoperations for which the only reason for reoperation was staged reconstruction.

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in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.3

REOPERATIVE REPORT: REASON FOR IMPLANT REMOVAL - FDA Item 12

Time Period: 0 - 24 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Removal (1,2)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
AT LEAST ONE EXPLANTATION	34 (100.0)	20 (100.0)	36 (100.0)	29 (100.0)	31 (100.0)	20 (100.0)	101 (100.0)	69 (100.0)
ASYMMETRY	0 (0.0)	0 (0.0)	10 (27.8)	9 (31.0)	3 (9.7)	3 (15.0)	13 (12.9)	12 (17.4)
BREAST PAIN	2 (5.9)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	1 (1.4)
CAPSULAR CONSTRACTURE III/IV	2 (5.9)	2 (10.0)	4 (11.1)	4 (13.8)	7 (22.6)	4 (20.0)	13 (12.9)	10 (14.5)
EXTRUSION	0 (0.0)	0 (0.0)	2 (5.6)	2 (6.9)	2 (6.5)	2 (10.0)	4 (4.0)	4 (5 8)
HEMATOMA	0 (0.0)	0 (0.0)	1 (2.8)	1 (3.4)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.4)
HYPERTROPHIC SCARRING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (5.0)	1 (1.0)	1 (1.4)
INFECTION	2 (5.9)	2 (10.0)	2 (5.6)	2 (6.9)	1 (3.2)	1 (5.0)	5 (5.0)	5 (7.2)
IMPLANT MALPOSITION/DISPLACEMENT	0 (0.0)	0 (0.0)	3 (8.3)	2 (6.9)	0 (0.0)	0 (0.0)	3 (3.0)	2 (2.9)
PATIENT REQUEST	22 (64.7)	12 (60.0)	11 (30.6)	7 (24.1)	12 (38.7)	7 (35.0)	45 (44.6)	26 (37.7)
WRINKLING	1 (2.9)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.4)
OTHER	1 (2.9)	1 (5.0)	3 (8.3)	3 (10.3)	3 (9.7)	2 (10.0)	7 (6.9)	6 (8.7)
False Positive MRI For Rupture	1 (2.9)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.4)
Lack Of Projection	0 (0.0)	0 (0.0)	1 (2.8)	1 (3.4)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.4)
Muscle Spasm	0 (0.0)	0 (0.0)	1 (2.8)	1 (3.4)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.4)
Pocket Tear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (5.0)	1 (1.0)	1 (1.4)
Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (2.8)	1 (3.4)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.4)
Symmastia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.5)	1 (5.0)	2 (2.0)	1 (1.4)
MISSING	4 (11.8)	2 (10.0)	0 (0.0)	0 (0.0)	2 (6.5)	1 (5.0)	6 (5.9)	3 (4.3)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_3_3.SAS

Creation Date, Time: 24AUG04 09:04

Note 1: Includes all implant removals with or without replacement reported up to 24 months post-implant surgery.
Note 2: Excludes reoperations for which the only reason for reoperation was staged reconstruction.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.3

REOPERATIVE REPORT: REASON FOR IMPLANT REMOVAL - FDA Item 12

Time Period: 0 - 36 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Removal (1,2)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
AT LEAST ONE EXPLANTATION	45 (100.0)	26 (100.0)	40 (100.0)	31 (100.0)	39 (100.0)	25 (100.0)	124 (100.0)	82 (100.0)
ASYMMETRY	0 (0.0)	0 (0.0)	10 (25.0)	9 (29.0)	3 (7.7)	3 (12.0)	13 (10.5)	12 (14.6)
BREAST PAIN	2 (4.4)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (1.2)
CAPSULAR CONSTRACTURE III/IV	5 (11.1)	5 (19.2)	4 (10.0)	4 (12.9)	11 (28.2)	7 (28.0)	20 (16.1)	16 (19.5)
EXTRUSION	0 (0.0)	0 (0.0)	2 (5.0)	2 (6.5)	2 (5.1)	2 (8.0)	4 (3.2)	4 (4.9)
HEMATOMA	0 (0.0)	0 (0.0)	1 (2.5)	1 (3.2)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.2)
HYPERTROPHIC SCARRING	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (4.0)	1 (0.8)	1 (1.2)
INFECTION	2 (4.4)	2 (7.7)	2 (5.0)	2 (6.5)	1 (2.6)	1 (4.0)	5 (4.0)	5 (6.1)
NECROSIS	2 (4.4)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (1.2)
IMPLANT MALPOSITION/DISPLACEMENT	0 (0.0)	0 (0.0)	3 (7.5)	2 (6.5)	0 (0.0)	0 (0.0)	3 (2.4)	2 (2 4)
PATIENT REQUEST	27 (60.0)	15 (57.7)	13 (32.5)	8 (25.8)	14 (35.9)	8 (32.0)	54 (43.5)	31 (37.8)
WRINKLING	1 (2.2)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.2)
OTHER	2 (4.4)	2 (7.7)	5 (12.5)	4 (12.9)	5 (12.8)	4 (16.0)	12 (9.7)	10 (12.2)
Abnormal Mammogram	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (4.0)	1 (0.8)	1 (1.2)
False Positive MRI For Rupture	1 (2.2)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.2)
Lack Of Projection	0 (0.0)	0 (0.0)	1 (2.5)	1 (3.2)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.2)
Muscle Spasm	0 (0.0)	0 (0.0)	1 (2.5)	1 (3.2)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.2)
Pocket Tear	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (4.0)	1 (0.8)	1 (1.2)
Recurrent Breast Cancer	0 (0.0)	0 (0.0)	1 (2.5)	1 (3.2)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.2)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_3_3.SAS Creation Date, Time: 24AUG04 09:04

Note 1: Includes all implant removals with or without replacement reported up to 36 months post-implant surgery.
Note 2: Excludes reoperations for which the only reason for reoperation was staged reconstruction.

' Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.3.3

REOPERATIVE REPORT: REASON FOR IMPLANT REMOVAL - FDA Item 12

Time Period: 0 - 36 Months

	Augmentation Patients		Reconstruction Patients		Revision Patients		Overall	
Reason for Removal (1,2)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)	No. of Implants n(%)	No. of Patients n(%)
Right Explanted So Left Done Also	1 (2.2)	1 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.2)
Suspected Rupture	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (4.0)	1 (0.8)	1 (1.2)
Symmastia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.1)	1 (4.0)	2 (1.6)	1 (1.2)
Too Large	0 (0.0)	0 (0.0)	2 (5.0)	1 (3.2)	0 (0.0)	0 (0.0)	2 (1.6)	1 (1.2)
MISSING	4 (8.9)	2 (7.7)	0 (0.0)	0 (0.0)	2 (5.1)	1 (4.0)	6 (4.8)	3 (3.7)

Note 1: Includes all implant removals with or without replacement reported up to 36 months post-implant surgery.
Note 2. Excludes reoperations for which the only reason for reoperation was staged reconstruction.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.4

REOPERATIVE REPORT: PRIMARY REASON FOR REOPERATION AFTER INITIAL EXPLANTATION AND REIMPLANTATION WITH STUDY DEVICE
OVERALL PATIENTS

Time Period: 0 - 36 Months

Primary Reason for Reoperation	No. of Reoperation n(%)	No. of Implants n(%)	No. of Patients n(%)
ASYMMETRY	2 (13.3)	2 (16.7)	1 (12.5)
CAPSULAR CONTRACTURE (BAKER III/IV)	2 (13 3)	2 (16.7)	2 (25.0)
EXTRUSION	1 (6.7)	1 (8.3)	1 (12.5)
HYPERTROPHIC SCARRING	4 (26.7)	3 (25.0)	2 (25.0)
OTHER	6 (40.0)	6 (50.0)	5 (62.5)
ABNORMAL MAMMOGRAM	1 (6.7)	1 (8.3)	1 (12.5)
INFECTION	1 (6.7)	1 (8.3)	1 (12.5)
PATIENT CHANGED TO SALINE	1 (6.7)	1 (8.3)	1 (12.5)
PATIENT REQUEST FOR REMOVAL	2 (13.3)	2 (16.7)	1 (12.5)
RIGHT INTRA-AREALOR DEPRESSION	1 (6.7)	1 (8.3)	1 (12.5)
TOTAL ASSESSED WITH REOPERATION AFTER INITIAL EXPLANTATION	15 (100.0)	12 (100.0)	8 (100.0)

Note 1: Excludes reoperations for which the only reason for reoperation was staged reconstruction.
Note 2: Percentages are based upon Total Assessed with Reoperation after Initial Explantation.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.5

GLOBAL SATISFACTION AMONG PATIENTS WHO HAVE HAD A REOPERATION
AUGMENTATION PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	29 (90.6%)	(0.805,1.000)
	No	2 (6.3%)	
	Missing/Unknown	1 (3.1%)	
	Total	32 (100.0%)	
1 Year	Yes	46 (93.9%)	(0.872,1.000)
	No	3 (6.1%)	
	Total	49 (100.0%)	
2 Year	Yes	61 (95.3%)	(0.901,1.000)
	No	3 (4.7%)	
	Total	64 (100.0%)	
3 Year	Yes	48 (92.3%)	(0.851,0.996)
	No	4 (7.7%)	
	Total	52 (100.0%)	

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Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.
Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.5

GLOBAL SATISFACTION AMONG PATIENTS WHO HAVE HAD A REOPERATION
OVERALL RECONSTRUCTION PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	21 (91.3%)	(0.778,1.000)
	No	2 (8.7%)	
	Total	23 (100.0%)	
1 Year	Yes	39 (97.5%)	(0.878,1.000)
	No	1 (2.5%)	
	Total	40 (100.0%)	
2 Year	Yes	51 (96.2%)	(0.862,1.000)
	No	1 (1.9%)	
	Missing/Unknown	1 (1.9%)	
	Total	53 (100.0%)	
3 Year	Yes	25 (96.2%)	(0.794,1.000)
	No	1 (3.8%)	
	Total	26 (100.0%)	

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Note 1. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.
Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.5

GLOBAL SATISFACTION AMONG PATIENTS WHO HAVE HAD A REOPERATION
DELAYED POST-MASTECTOMY PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	12 (100.0%)	(1.000,1.000)
	Total	12 (100.0%)	
1 Year	Yes	19 (95.0%)	(0.854,1.000)
	No	1 (5.0%)	
	Total	20 (100.0%)	
2 Year	Yes	24 (96.0%)	(0.883,1.000)
	Missing/Unknown	1 (4.0%)	
	Total	25 (100.0%)	
3 Year	Yes	9 (90.0%)	(0.714,1.000)
	No	1 (10.0%)	
	Total	10 (100.0%)	

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Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.
Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.5

GLOBAL SATISFACTION AMONG PATIENTS WHO HAVE HAD A REOPERATION
IMMEDIATE POST-MASTECTOMY PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	9 (90.0%)	----
	No	1 (10.0%)	
	Total	10 (100.0%)	
1 Year	Yes	16 (100.0%)	----
	Total	16 (100.0%)	
2 Year	Yes	19 (100.0%)	----
	Total	19 (100.0%)	
3 Year	Yes	12 (100.0%)	----
	Total	12 (100.0%)	

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.
Note 2: Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.5

GLOBAL SATISFACTION AMONG PATIENTS WHO HAVE HAD A REOPERATION
REVISION PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	17 (89.5%)	(0.757,1.000)
	No	2 (10.5%)	
	Total	19 (100.0%)	
1 Year	Yes	26 (86.7%)	(0.745,0.988)
	No	2 (6.7%)	
	Missing/Unknown	2 (6.7%)	
	Total	30 (100.0%)	
2 Year	Yes	36 (94.7%)	(0.876,1.000)
	No	2 (5.3%)	
	Total	38 (100.0%)	
3 Year	Yes	26 (92.9%)	(0.833,1.000)
	No	2 (7.1%)	
	Total	28 (100 0%)	

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.
Note 2. Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

`Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.5

GLOBAL SATISFACTION AMONG PATIENTS WHO HAVE HAD A REOPERATION
OVERALL PATIENTS

Postoperative Visit	Would Patient Have Surgery Again?	n (%)	95% Confidence Interval for Proportion Who Would Have the Surgery Again
6 Months	Yes	67 (90.5%)	(0 835,0.978)
	No	6 (8.1%)	
	Missing/Unknown	1 (1.4%)	
	Total	74 (100.0%)	
1 Year	Yes	111 (93.3%)	(0.871,0.974)
	No	6 (5.0%)	
	Missing/Unknown	2 (1.7%)	
	Total	119 (100.0%)	
2 Year	Yes	148 (95.5%)	(0.911,0.986)
	No	6 (3.9%)	
	Missing/Unknown	1 (0.6%)	
	Total	155 (100.0%)	
3 Year	Yes	99 (93.4%)	(0.872,0.979)
	No	7 (6.6%)	
	Total	106 (100.0%)	

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Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.
Note 2. Immediate post-mastectomy patients are excluded from the calculation of confidence interval for the Overall Reconstruction Patients and Overall Patients.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT. PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
AUGMENTATION PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	0 (0.0)	0 (0.0)
Capsulectomy	16 (22.5)	13 (24.5)
Capsulorrhaphy	3 (4.2)	2 (3.8)
Capsulotomy	8 (11.3)	5 (9.4)
Create Inframmary Fold	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	14 (19.7)	8 (15.1)
Implant Removal (Without Replacement)	8 (11.3)	5 (9.4)
Implant Reposition	0 (0.0)	0 (0.0)
Incision and Drainage	10 (14.1)	10 (18.9)
Mastopexy	0 (0.0)	0 (0.0)
Nipple Related Procedure (unplanned)	1 (1.4)	1 (1.9)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)
Revision Of Wound Closure	3 (4.2)	3 (5.7)
Scar Revision	5 (7.0)	4 (7.5)
Skin Adjustment	3 (4.2)	2 (3.8)
Total Assessed with Additional Surgical Procedures	71 (100.0)	53 (100.0)

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T09_6 SAS Creation Date, Time: 26AUG04 10:14

Note. Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT, PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
AUGMENTATION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	1 (1.0)	1 (1.5)
Capsulectomy	21 (21.2)	15 (22.1)
Capsulorrhaphy	3 (3.0)	2 (2.9)
Capsulotomy	12 (12.1)	8 (11.8)
Create Inframmary Fold	0 (0.0)	0 (0.0)
Excise Breast Mass	1 (1.0)	1 (1.5)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	20 (20.2)	12 (17.6)
Implant Removal (Without Replacement)	14 (14.1)	8 (11.8)
Implant Reposition	2 (2.0)	1 (1.5)
Incision and Drainage	8 (8.1)	8 (11.8)
Mastopexy	0 (0.0)	0 (0.0)
Nipple Related Procedure (unplanned)	1 (1.0)	1 (1.5)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)
Revision Of Wound Closure	3 (3.0)	3 (4.4)
Scar Revision	10 (10.1)	6 (8.8)
Skin Adjustment	3 (3.0)	2 (2.9)
Total Assessed with Additional Surgical Procedures	99 (100.0)	68 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time. 26AUG04 10:14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
AUGMENTATION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	1 (0.9)	1 (1.3)
Breast Mass Excision Dx· Fibroadenoma	0 (0.0)	0 (0.0)
Capsulectomy	19 (16.5)	14 (17.7)
Capsulorrhaphy	3 (2.6)	2 (2.5)
Capsulotomy	14 (12.2)	10 (12.7)
Create Inframmary Fold	0 (0.0)	0 (0.0)
Excise Breast Mass	2 (1.7)	2 (2.5)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	24 (20.9)	14 (17.7)
Implant Removal (Without Replacement)	21 (18.3)	12 (15.2)
Implant Reposition	2 (1.7)	1 (1.3)
Incision and Drainage	8 (7.0)	8 (10.1)
Mastopexy	0 (0.0)	0 (0.0)
Needle Aspiration	0 (0.0)	0 (0.0)
Nipple Related Procedure (unplanned)	1 (0.9)	1 (1.3)
Open Incision To Rule Out Implant Rupture	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)
Revision Of Wound Closure	3 (2.6)	3 (3.8)
Scar Revision	13 (11.3)	8 (10.1)
Skin Adjustment	4 (3.5)	3 (3.8)
Total Assessed with Additional Surgical Procedures	115 (100.0)	79 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time. 26AUG04 10.14

Note. Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note· Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
RECONSTRUCTION PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	6 (9.8)	5 (10.4)
Capsulectomy	5 (8.2)	4 (8.3)
Capsulorrhaphy	1 (1.6)	1 (2.1)
Capsulotomy	5 (8.2)	4 (8.3)
Create Inframmary Fold	1 (1.6)	1 (2.1)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	17 (27 9)	13 (27.1)
Implant Removal (Without Replacement)	9 (14.8)	7 (14.6)
Implant Reposition	2 (3.3)	2 (4.2)
Incision and Drainage	1 (1.6)	1 (2.1)
Mastopexy	1 (1.6)	1 (2.1)
Nipple Related Procedure (unplanned)	1 (1.6)	1 (2.1)
Removal Of Nodule On Chest Wall	2 (3.3)	1 (2.1)
Revision Of Wound Closure	1 (1.6)	1 (2.1)
Scar Revision	0 (0.0)	0 (0.0)
Skin Adjustment	9 (14.8)	6 (12.5)
Total Assessed with Additional Surgical Procedures	61 (100 0)	48 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time. 26AUG04 10:14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
RECONSTRUCTION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	8 (10.0)	7 (11.1)
Capsulectomy	5 (6.3)	4 (6.3)
Capsulorrhaphy	1 (1.3)	1 (1.6)
Capsulotomy	5 (6.3)	4 (6.3)
Create Inframmary Fold	1 (1.3)	1 (1.6)
Excise Breast Mass	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	23 (28.8)	18 (28.6)
Implant Removal (Without Replacement)	13 (16.3)	11 (17.5)
Implant Reposition	2 (2.5)	2 (3.2)
Incision and Drainage	1 (1.3)	1 (1.6)
Mastopexy	3 (3.8)	2 (3.2)
Nipple Related Procedure (unplanned)	1 (1.3)	1 (1.6)
Removal Of Nodule On Chest Wall	2 (2.5)	1 (1.6)
Revision Of Breast / External To Pocket	2 (2.5)	1 (1.6)
Revision Of Wound Closure	1 (1.3)	1 (1.6)
Scar Revision	3 (3.8)	2 (3.2)
Skin Adjustment	9 (11.3)	6 (9.5)
Total Assessed with Additional Surgical Procedures	80 (100.0)	63 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10:14

Note. Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
RECONSTRUCTION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	8 (9.8)	7 (10.9)
Breast Mass Excision Dx: Fibroadenoma	1 (1.2)	0 (0.0)
Capsulectomy	3 (3.7)	3 (4.7)
Capsulorrhaphy	1 (1.2)	1 (1.6)
Capsulotomy	5 (6.1)	4 (6.3)
Create Inframmary Fold	1 (1.2)	1 (1.6)
Excise Breast Mass	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	0 (0.0)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	0 (0.0)	0 (0.0)
Implant Removal (With Replacement)	23 (28.0)	18 (28.1)
Implant Removal (Without Replacement)	17 (20.7)	13 (20.3)
Implant Reposition	2 (2.4)	2 (3.1)
Incision and Drainage	2 (2.4)	2 (3.1)
Mastopexy	1 (1.2)	1 (1.6)
Needle Aspiration	0 (0.0)	0 (0.0)
Nipple Related Procedure (unplanned)	1 (1.2)	1 (1.6)
Open Incision To Rule Out Implant Rupture	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	2 (2.4)	1 (1.6)
Revision Of Breast / External To Pocket	2 (2.4)	1 (1.6)
Revision Of Wound Closure	1 (1.2)	1 (1.6)
Scar Revision	3 (3.7)	2 (3.1)
Skin Adjustment	9 (11.0)	6 (9.4)
Total Assessed with Additional Surgical Procedures	82 (100.0)	64 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10:14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
REVISION PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	5 (10.9)	5 (15.6)
Capsulectomy	6 (13.0)	4 (12.5)
Capsulorrhaphy	0 (0.0)	0 (0.0)
Capsulotomy	6 (13.0)	4 (12.5)
Create Inframmary Fold	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	2 (4.3)	1 (3.1)
Implant Removal (With Replacement)	12 (26.1)	8 (25.0)
Implant Removal (Without Replacement)	6 (13.0)	4 (12.5)
Implant Reposition	0 (0.0)	0 (0.0)
Incision and Drainage	5 (10.9)	4 (12.5)
Mastopexy	0 (0.0)	0 (0.0)
Nipple Related Procedure (unplanned)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)
Revision Of Wound Closure	1 (2.2)	1 (3.1)
Scar Revision	1 (2.2)	0 (0.0)
Skin Adjustment	2 (4.3)	1 (3.1)
Total Assessed with Additional Surgical Procedures	46 (100.0)	32 (100.0)

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10.14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
REVISION PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	5 (7.7)	5 (11.6)
Capsulectomy	6 (9.2)	4 (9.3)
Capsulorrhaphy	0 (0.0)	0 (0.0)
Capsulotomy	7 (10.8)	5 (11.6)
Create Inframmary Fold	0 (0.0)	0 (0.0)
Excise Breast Mass	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	1 (1.5)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	1 (1.5)	1 (2.3)
Implant Removal (With Replacement)	18 (27.7)	12 (27.9)
Implant Removal (Without Replacement)	13 (20.0)	8 (18.6)
Implant Reposition	2 (3.1)	1 (2.3)
Incision and Drainage	4 (6.2)	3 (7.0)
Mastopexy	0 (0.0)	0 (0.0)
Nipple Related Procedure (unplanned)	0 (0.0)	0 (0.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)
Revision Of Wound Closure	1 (1.5)	1 (2.3)
Scar Revision	3 (4.6)	1 (2 3)
Skin Adjustment	4 (6.2)	2 (4.7)
Total Assessed with Additional Surgical Procedures	65 (100.0)	43 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10:14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
REVISION PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No of Patients n(%)
Biopsy	4 (5.1)	4 (7.8)
Breast Mass Excision Dx: Fibroadenoma	0 (0.0)	0 (0.0)
Capsulectomy	6 (7.7)	4 (7.8)
Capsulorrhaphy	0 (0.0)	0 (0.0)
Capsulotomy	7 (9.0)	5 (9.8)
Create Inframmary Fold	0 (0.0)	0 (0.0)
Excise Breast Mass	0 (0.0)	0 (0.0)
Excision Of Skin Lesion	1 (1.3)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	1 (1.3)	1 (2.0)
Implant Removal (With Replacement)	21 (26.9)	14 (27.5)
Implant Removal (Without Replacement)	18 (23.1)	11 (21.6)
Implant Reposition	4 (5.1)	2 (3.9)
Incision and Drainage	4 (5.1)	3 (5.9)
Mastopexy	0 (0.0)	0 (0.0)
Needle Aspiration	1 (1.3)	1 (2.0)
Nipple Related Procedure (unplanned)	1 (1.3)	0 (0.0)
Open Incision To Rule Out Implant Rupture	1 (1.3)	1 (2.0)
Removal Of Nodule On Chest Wall	0 (0.0)	0 (0.0)
Revision Of Breast / External To Pocket	0 (0.0)	0 (0.0)
Revision Of Wound Closure	1 (1.3)	1 (2.0)
Scar Revision	4 (5.1)	2 (3.9)
Skin Adjustment	4 (5.1)	2 (3.9)
Total Assessed with Additional Surgical Procedures	78 (100.0)	51 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10:14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
OVERALL PATIENTS

Time Period: 0 - 12 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	11 (6.2)	10 (7.5)
Capsulectomy	27 (15.2)	21 (15.8)
Capsulorrhaphy	4 (2.2)	3 (2.3)
Capsulotomy	19 (10.7)	13 (9.8)
Create Inframmary Fold	1 (0.6)	1 (0.8)
Excision Of Skin Lesion	2 (1.1)	1 (0.8)
Implant Removal (With Replacement)	43 (24.2)	29 (21 8)
Implant Removal (Without Replacement)	23 (12.9)	16 (12.0)
Implant Reposition	2 (1.1)	2 (1.5)
Incision and Drainage	16 (9.0)	15 (11.3)
Mastopexy	1 (0.6)	1 (0.8)
Nipple Related Procedure (unplanned)	2 (1.1)	2 (1.5)
Removal Of Nodule On Chest Wall	2 (1.1)	1 (0.8)
Revision Of Wound Closure	5 (2.8)	5 (3.8)
Scar Revision	6 (3.4)	4 (3.0)
Skin Adjustment	14 (7.9)	9 (6.8)
Total Assessed with Additional Surgical Procedures	178 (100.0)	133 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10:14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
OVERALL PATIENTS

Time Period: 0 - 24 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	14 (5.7)	13 (7.5)
Capsulectomy	32 (13.1)	23 (13.2)
Capsulorrhaphy	4 (1.6)	3 (1.7)
Capsulotomy	24 (9.8)	17 (9.8)
Create Inframmary Fold	1 (0.4)	1 (0.6)
Excise Breast Mass	1 (0.4)	1 (0.6)
Excision Of Skin Lesion	1 (0.4)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.4)	1 (0.6)
Implant Removal (With Replacement)	61 (25.0)	42 (24.1)
Implant Removal (Without Replacement)	40 (16.4)	27 (15.5)
Implant Reposition	6 (2.5)	4 (2.3)
Incision and Drainage	13 (5.3)	12 (6.9)
Mastopexy	3 (1.2)	2 (1.1)
Nipple Related Procedure (unplanned)	2 (0.8)	2 (1.1)
Removal Of Nodule On Chest Wall	2 (0.8)	1 (0.6)
Revision Of Breast / External To Pocket	2 (0.8)	1 (0.6)
Revision Of Wound Closure	5 (2.0)	5 (2.9)
Scar Revision	16 (6.6)	9 (5.2)
Skin Adjustment	16 (6.6)	10 (5.7)
Total Assessed with Additional Surgical Procedures	244 (100.0)	174 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10.14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 9.6

REOPERATIVE REPORT: PRIMARY TYPE OF ADDITIONAL SURGICAL PROCEDURES - FDA Item 14
OVERALL PATIENTS

Time Period: 0 - 36 Months

Type of Additional Surgical Procedure	No. of Implants n(%)	No. of Patients n(%)
Biopsy	13 (4.7)	12 (6.2)
Breast Mass Excision Dx: Fibroadenoma	1 (0.4)	0 (0.0)
Capsulectomy	28 (10.2)	21 (10.8)
Capsulorrhaphy	4 (1.5)	3 (1.5)
Capsulotomy	26 (9.5)	19 (9.8)
Create Inframmary Fold	1 (0.4)	1 (0.5)
Excise Breast Mass	2 (0.7)	2 (1.0)
Excision Of Skin Lesion	1 (0.4)	0 (0.0)
Exploration Right Breast With Evacuation Of Hematoma	1 (0.4)	1 (0.5)
Implant Removal (With Replacement)	68 (24.7)	46 (23.7)
Implant Removal (Without Replacement)	56 (20.4)	36 (18.6)
Implant Reposition	8 (2.9)	5 (2.6)
Incision and Drainage	14 (5.1)	13 (6.7)
Mastopexy	1 (0.4)	1 (0.5)
Needle Aspiration	1 (0.4)	1 (0.5)
Nipple Related Procedure (unplanned)	3 (1.1)	2 (1.0)
Open Incision To Rule Out Implant Rupture	1 (0 4)	1 (0.5)
Removal Of Nodule On Chest Wall	2 (0.7)	1 (0.5)
Revision Of Breast / External To Pocket	2 (0.7)	1 (0.5)
Revision Of Wound Closure	5 (1 8)	5 (2.6)
Scar Revision	20 (7.3)	12 (6.2)
Skin Adjustment	17 (6.2)	11 (5.7)
Total Assessed with Additional Surgical Procedures	275 (100.0)	194 (100.0)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T09_6.SAS Creation Date, Time: 26AUG04 10:14

Note: Implant hierarchy levels as follows - Implant Removal (Without Replacement),Implant Removal (With Replacement),Capsulectomy,Capsulotomy,Incision and Drainage,Exploration Right Breast With Evacuation Of Hematoma,Revision Of Wound Closure,Flap Coverage Of Expander,Skin Adjustment,Kenalog Injection, Mastopexy,Nipple Related Procedure (unplanned),Create Inframmary Fold,Revision Of Breast / External To Pocket,Excise Breast Mass,Excision Of Skin Lesion, Removal Of Nodule On Chest Wall,Biopsy,Implant Reposition,Capsulorrhaphy,Implant Pocket Revision,Scar Revision,and (Needle Aspiration and Open Incision To Rule Out Implant Rupture).

Note: Percentages are based upon Total Assessed with Additional Surgical Procedures.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1

INFECTION: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	0.896	0.0444	1.005	0.8947		**
Race		0.9978		0.6816		
Caucasian	1.000 (reference)		1.000 (reference)			
Other	0.000		0.608			
Smoking Status		0.2590		0.6546		
No	1.000 (reference)		1.000 (reference)			
Yes	0.233		1.713			
Surgical Approach		0.3127		0.3768		
Inframammary	1 000 (reference)		1.000 (reference)			
Periareoloar	22.431		13.056			
Transaxillary	0.000		N/A			
Mastectomy Scar	N/A		0 370			
Other/Mixed	0.000		0.554			
Surgical Placement		0.9908		0.9620		
Submuscular	1 000 (reference)		1.000 (reference)			
Subglandular	1.173		0.000			
Subpectoral	0.000		1.764			
Other/Mixed	N/A		0.000			

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note. Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1

INFECTION: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.843	0.1569	0.965	0.7630		
Surface Type						
Smooth	1.000 (reference)		1.000 (reference)			
Textured	0.236		9.690			
Mixed	N/A		N/A			
Prior Tissue Expander*				0.0069		
Yes			1.000 (reference)			
No	N/A		0.053			
Irrigation Solutions Used in Pocket		0.8652		0.3678		
Saline Only	1.000 (reference)		1.000 (reference)			
Steroid Only	>100		N/A			
Antibiotic Only	4.762		0.962			
Drug Only	>100		0.000			
Other	11.521		4.367			

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1

INFECTION: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.4401		0.4474		
<=349 cc	N/A		N/A			
350-399 cc	7.221		7.405			
400-499 cc	13.433		0.000			
500-599 cc	9.004		3.763			
>=600 cc	0.000		2.840			
Site		0.9634		0.1331		
Pooled Site	1.000 (reference)		1.000 (reference)			
Site 1	0.000					
Site 2	0.000		N/A			
Site 3	0.000		N/A			
Site 4	>100		N/A			
Site 5	0.000		N/A			
Site 7	2.023		N/A			
Site 8	0.000		N/A			
Site 10	0.034		N/A			
Site 12	0.000		N/A			
Site 13	0.000		N/A			
Site 15	0.002		N/A			
Site 18	0.000		N/A			
Site 19	N/A		3.176			
Site 23	0.011		N/A			
Site 30	N/A		0.042			

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1

INFECTION: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 33	N/A		8.650			
Site 48	N/A		0.000			

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2

RUPTURE: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)		**		**	1.153	0.3530
Race						0.9992
Caucasian					1.000 (reference)	
Other					0.000	
Smoking Status						0.7771
No					1.000 (reference)	
Yes					0.547	
Surgical Approach						0.9825
Inframammary					1.000 (reference)	
Periareoloar					0.380	
Transaxillary					19.820	
Mastectomy Scar					0.000	
Other/Mixed					0.000	
Surgical Placement						0.6088
Submuscular					1.000 (reference)	
Subglandular					>100	
Subpectoral					>100	
Other/Mixed					0.259	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 27AUG04 11:57

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Too Few patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2

RUPTURE: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)					0.849	0.7180
Surface Type						
Smooth					1.000 (reference)	
Textured					0.743	
Mixed					N/A	
Prior Tissue Expander*						
Yes						
No					N/A	
Irrigation Solutions Used in Pocket						0.6522
Saline Only					1.000 (reference)	
Steroid Only					N/A	
Antibiotic Only					34.716	
Drug Only					0.000	
Other					3.273	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 27AUG04 11:57

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Too Few patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2

RUPTURE: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size						0.8057
<-349 cc					N/A	
350-399 cc					0.000	
400-499 cc					3.765	
500-599 cc					0.000	
>=600 cc					23.272	
Site						1.0000
Pooled Site					1.000 (reference)	
Site 1						
Site 2					0.000	
Site 3					N/A	
Site 4					N/A	
Site 5					N/A	
Site 7					N/A	
Site 8					N/A	
Site 10					0.000	
Site 12					N/A	
Site 13					N/A	
Site 15					N/A	
Site 18					N/A	
Site 19					0.000	
Site 23					N/A	
Site 30					N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 27AUG04 11:57

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Too Few patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2

RUPTURE: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 33					N/A	
Site 48					N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 27AUG04 11:57

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Too Few patients reported the event. Consequently no analyses were performed.

· Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.3

CAPSULAR CONTRACTURE GRADE III, OR IV: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	1.018	0.3613	1.055	0.0788	0.995	0.7963
Race		0.8529		0.0878		0.1345
Caucasian	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Other	0.907		3.654		2.465	
Smoking Status		0.7249		0.9962		0.8945
No	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Yes	1.154		0.000		1.069	
Surgical Approach		0.4468		1.0000		0.9571
Inframammary	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Periareoloar	0.985		0.000		0.615	
Transaxillary	0.579		N/A		0.000	
Mastectomy Scar	N/A		1.028		0.916	
Other/Mixed	3.206		0.993		1.030	
Surgical Placement		0.0267		0.8926		0.7679
Submuscular	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Subglandular	3.859		1.148		1.591	
Other/Mixed	N/A		0.000		0.000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.3

CAPSULAR CONTRACTURE GRADE III, OR IV. COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	0.938	0.5721	0.969	0.7867	1.099	0.2871
Surface Type						
Smooth	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Textured	0.000		3.366		1.373	
Mixed	N/A		N/A		N/A	
Prior Tissue Expander*				0.2322		
Yes			1.000 (reference)			
No	N/A		2.743		N/A	
Irrigation Solutions Used in Pocket		0.0886		0.0086		0.3311
Saline Only	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Steroid Only	40.888		N/A		N/A	
Antibiotic Only	2.088		0.077		0.342	
Drug Only	17.519		0.000		0.000	
Other	7.869		0.066		0.667	

* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.3

CAPSULAR CONTRACTURE GRADE III, OR IV: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.8161		0.3937		0.2918
<=349 cc	N/A		N/A		N/A	
350-399 cc	0.798		2.400		2.414	
400-499 cc	0.618		1.063		1.127	
500-599 cc	1.172		0.759		1.946	
>=600 cc	0.000		3.934		0.696	
Site		0.4023		0.1279		0.0011
Pooled Site	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Site 1	>100					
Site 2	0.906		N/A		1.500	
Site 3	1.266		N/A		N/A	
Site 4	>100		N/A		N/A	
Site 5	0.629		N/A		N/A	
Site 7	0.000		N/A		N/A	
Site 8	>100		N/A		N/A	
Site 10	0.153		N/A		10.032	
Site 12	0.000		N/A		N/A	
Site 13	0.000		N/A		N/A	
Site 15	0.936		N/A		N/A	
Site 18	1.259		N/A		N/A	
Site 19	N/A		3.835		5.121	
Site 23	0.089		N/A		N/A	
Site 30	N/A		0.000		N/A	
Site 33	N/A		0.047		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time, 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not.associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.3

CAPSULAR CONTRACTURE GRADE III, OR IV: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 48	N/A		1.930		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4

NIPPLE SENSATION CHANGES. COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	1.011	0.5731		**	0.985	0.5917
Race		0.3468				0.9957
Caucasian	1.000 (reference)				1.000 (reference)	
Other	1.439				0.000	
Smoking Status		0.2344				0.4434
No	1.000 (reference)				1.000 (reference)	
Yes	0.610				0.521	
Surgical Approach		0.7290				0.9969
Inframammary	1.000 (reference)				1.000 (reference)	
Periareoloar	0.852				0.800	
Transaxillary	0.273				0.000	
Mastectomy Scar	N/A				0.000	
Other/Mixed	0.667				1.221	
Surgical Placement		0.6951				0.4454
Submuscular	1.000 (reference)				1.000 (reference)	
Subglandular	1.104				2.530	
Subpectoral	0.706				2.451	
Other/Mixed	N/A				0.000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4

NIPPLE SENSATION CHANGES: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.174	0.0829			1.050	0.6800
Surface Type						
Smooth	1.000 (reference)				1.000 (reference)	
Textured	1.126				0.304	
Mixed	N/A				N/A	
Prior Tissue Expander*						
Yes						
No	N/A				N/A	
Irrigation Solutions Used in Pocket		0.7565				0.8674
Saline Only	1.000 (reference)				1.000 (reference)	
Steroid Only	0.000				N/A	
Antibiotic Only	2.246				0.766	
Drug Only	2.430				0.000	
Other	1.494				0.557	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08.58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4

NIPPLE SENSATION CHANGES: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.2823				0 9586
<=349 cc	N/A				N/A	
350-399 cc	0.747				0.658	
400-499 cc	0.470				0.740	
500-599 cc	1.875				0.872	
>=600 cc	0.000				0.479	
Site		0.5764				0.9392
Pooled Site	1.000 (reference)				1.000 (reference)	
Site 1	1.961					
Site 2	1.704				0.000	
Site 3	0.226				N/A	
Site 4	0.382				N/A	
Site 5	0.209				N/A	
Site 7	0.352				N/A	
Site 8	2.312				N/A	
Site 10	0.218				1.533	
Site 12	0.715				N/A	
Site 13	1.585				N/A	
Site 15	0.767				N/A	
Site 18	0.814				N/A	
Site 19	N/A				1.689	
Site 23	1.078				N/A	
Site 30	N/A				N/A	

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4

NIPPLE SENSATION CHANGES: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 33	N/A				N/A	
Site 48	N/A				N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS
Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.5

BREAST SENSATION CHANGES. COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	0 984	0.7294		**	0.909	0.2421
Race		0.2680				0.9986
Caucasian	1.000 (reference)				1.000 (reference)	
Other	2.672				0.000	
Smoking Status		0.8433				0.9981
No	1.000 (reference)				1.000 (reference)	
Yes	0.838				0.000	
Surgical Approach		0.9759				0.7355
Inframammary	1.000 (reference)				1.000 (reference)	
Periareoloar	0.579				6.148	
Transaxillary	0.000				0.000	
Mastectomy Scar	N/A				0.000	
Other/Mixed	0.000				15.398	
Surgical Placement		0.9758				0 9421
Submuscular	1.000 (reference)				1.000 (reference)	
Subglandular	0.775				0.392	
Subpectoral	0.825				0.381	
Other/Mixed	N/A				0.000	

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10 5

BREAST SENSATION CHANGES: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.107	0.5922			0.711	0.3371
Surface Type						
Smooth	1.000 (reference)				1.000 (reference)	
Textured	0.518				1.666	
Mixed	N/A				N/A	
Prior Tissue Expander*						
Yes						
No	N/A				N/A	
Irrigation Solutions Used in Pocket		0.3731				0.9874
Saline Only	1.000 (reference)				1.000 (reference)	
Steroid Only	>100				N/A	
Antibiotic Only	>100				1.205	
Drug Only	>100				0.000	
Other	>100				1.897	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.5

BREAST SENSATION CHANGES: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.7209				0.9531
<=349 cc	N/A				N/A	
350-399 cc	0.201				0.230	
400-499 cc	0.781				0.688	
500-599 cc	0.000				0.000	
>=600 cc	0.055				0.000	
Site		0.9506				0.5043
Pooled Site	1.000 (reference)				1.000 (reference)	
Site 1	0.000					
Site 2	40.409				0.000	
Site 3	0.000				N/A	
Site 4	0.639				N/A	
Site 5	0.664				N/A	
Site 7	0.000				N/A	
Site 8	>100				N/A	
Site 10	0.000				0.000	
Site 12	0.000				N/A	
Site 13	29.526				N/A	
Site 15	9.771				N/A	
Site 18	0.000				N/A	
Site 19	N/A				84.457	
Site 23	12.213				N/A	
Site 30	N/A				N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time. 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.5

BREAST SENSATION CHANGES: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 33	N/A				N/A	
Site 48	N/A				N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS
Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.6

EXPLANTATION (REMOVAL) FOR ANY REASON REGARDLESS OF REPLACEMENT. COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	1.003	0.9157	1.044	0.0726	0.961	0.1200
Race		0.3529		0.0043		0.3529
Caucasian	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Other	0.378		5.326		0.343	
Smoking Status		0.8412		0.0606		0.6700
No	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Yes	0.896		0.118		0.763	
Surgical Approach		0.0433		0.6222		0.9947
Inframammary	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Periareoloar	0.785		0.578		1.176	
Transaxillary	2.925		N/A		0.000	
Mastectomy Scar	N/A		0.423		1.263	
Other/Mixed	8.460		0.887		0.839	
Surgical Placement		0.8082		0.1727		0.6849
Submuscular	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Subglandular	0.804		1.593		0.588	
Subpectoral	0.507		0.196		0.477	
Other/Mixed	N/A		1.359		0.000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08.58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.6

EXPLANTATION (REMOVAL) FOR ANY REASON REGARDLESS OF REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	0.962	0.8476	1.070	0.4608	1.085	0.4386
Surface Type						
Smooth	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Textured	1.951		0.545		0.670	
Mixed	N/A		N/A		N/A	
Prior Tissue Expander*				0.7972		
Yes			1.000 (reference)			
No	N/A		1.197		N/A	
Irrigation Solutions Used in Pocket		0.8003		0.0783		0.9705
Saline Only	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Steroid Only	0.000		N/A		N/A	
Antibiotic Only	1.551		0.186		0.760	
Drug Only	9.260		2.992		0.000	
Other	4.635		0.470		0.973	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.6

EXPLANTATION (REMOVAL) FOR ANY REASON REGARDLESS OF REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0 3677		0.1644		0.2399
<=349 cc	N/A		N/A		N/A	
350-399 cc	2.118		3.872		2.246	
400-499 cc	1.735		1.390		1.571	
500-599 cc	5.918		2.620		3.030	
>=600 cc	0.000		2.927		0.333	
Site		0.9781		0.1984		0.2855
Pooled Site	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Site 1	1.436					
Site 2	0.546		N/A		0.000	
Site 3	0.407		N/A		N/A	
Site 4	0.484		N/A		N/A	
Site 5	0.000		N/A		N/A	
Site 7	1.739		N/A		N/A	
Site 8	0.000		N/A		N/A	
Site 10	0.281		N/A		3.844	
Site 12	0.000		N/A		N/A	
Site 13	0.363		N/A		N/A	
Site 15	0.794		N/A		N/A	
Site 18	0.266		N/A		N/A	
Site 19	N/A		4.797		1.987	
Site 23	2.027		N/A		N/A	
Site 30	N/A		0.000		N/A	
Site 33	N/A		0.907		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.6

EXPLANTATION (REMOVAL) FOR ANY REASON REGARDLESS OF REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 48	N/A		4.362		N/A	

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* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10 7

EXPLANTATION (REMOVAL) FOR ANY REASON WITH REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	1.017	0.6345	1.019	0.5436	0.982	0.5771
Race		0.6967		0.0797		0.9654
Caucasian	1.000 (reference)		1.000 (reference)		1 000 (reference)	
Other	0.657		4.799		1.053	
Smoking Status		0.6497		0.9921		0 2458
No	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Yes	0.728		0.000		0.272	
Surgical Approach		0.0885		0.8382		0.9820
Inframammary	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Periareoloar	0.856		4.250		1.244	
Transaxillary	3.050		N/A		0.000	
Mastectomy Scar	N/A		1.338		1.063	
Other/Mixed	11.728		1.385		1.733	
Surgical Placement		0.8380		0.1749		0.9776
Submuscular	1.000 (reference)		1.000 (reference)		1 000 (reference)	
Subglandular	0.665		1.412		1.339	
Subpectoral	0.600		0.183		1.280	
Other/Mixed	N/A		2.952		0.000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time. 24AUG04 08.58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.7

EXPLANTATION (REMOVAL) FOR ANY REASON WITH REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	0.879	0.6535	0.985	0.9132	1.026	0.8556
Surface Type						
Smooth	1.000 (reference)		1.000 (reference)		1 000 (reference)	
Textured	1.308		0.556		0.456	
Mixed	N/A		N/A		N/A	
Prior Tissue Expander*				0.8406		
Yes			1.000 (reference)			
No	N/A		0.815		N/A	
Irrigation Solutions Used in Pocket		0.9532		0.1250		0.9796
Saline Only	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Steroid Only	0.000		N/A		N/A	
Antibiotic Only	0.780		0.388		0.705	
Drug Only	1.075		19.843		0.000	
Other	2.196		0.763		0.777	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.7

EXPLANTATION (REMOVAL) FOR ANY REASON WITH REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.5514		0.1475		0.9742
<=349 cc	N/A		N/A		N/A	
350-399 cc	3.010		4.962		1.401	
400-499 cc	1.913		0.640		1.361	
500-599 cc	5.651		1.256		1.888	
>=600 cc	0.000		0.640		0.000	
Site		0.9995		0.1368		0.6454
Pooled Site	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Site 1	0.825					
Site 2	0.383		N/A		0.000	
Site 3	0.561		N/A		N/A	
Site 4	1.176		N/A		N/A	
Site 5	0.000		N/A		N/A	
Site 7	1.765		N/A		N/A	
Site 8	0.000		N/A		N/A	
Site 10	0.326		N/A		3.524	
Site 12	0.000		N/A		N/A	
Site 13	0.469		N/A		N/A	
Site 15	0.809		N/A		N/A	
Site 18	0.000		N/A		N/A	
Site 19	N/A		11.535		1.436	
Site 23	0.399		N/A		N/A	
Site 30	N/A		0.000		N/A	
Site 33	N/A		2.364		N/A	

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* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.7

EXPLANTATION (REMOVAL) FOR ANY REASON WITH REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 48	N/A		5.963		N/A	

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* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.8

EXPLANTATION (REMOVAL) FOR ANY REASON WITHOUT REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	0.977	0.5805	1.092	0.0295	0.933	0.0969
Race		0.9960		0.0121		0.9972
Caucasian	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Other	0.000		8.783		0.000	
Smoking Status		0.9363		0.2231		0.3123
No	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Yes	0.923		0.220		2.364	
Surgical Approach		0.7874		0.3203		0.9960
Inframammary	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Periareoloar	0.731		0.000		1.660	
Transaxillary	2.346		N/A		0.000	
Mastectomy Scar	N/A		0.140		0.932	
Other/Mixed	4.548		0.746		0.000	
Surgical Placement		0.9980		0.4800		0.3433
Submuscular	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Subglandular	0.919		3.385		0.151	
Subpectoral	0.000		0.167		0.000	
Other/Mixed	N/A		0.000		0.000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.8

EXPLANTATION (REMOVAL) FOR ANY REASON WITHOUT REPLACEMENT. COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.085	0.7608	1.164	0.2457	1.232	0.1945
Surface Type						
Smooth	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Textured	1.854		0.428		1.116	
Mixed	N/A		N/A		N/A	
Prior Tissue Expander*				0.5787		
Yes			1.000 (reference)			
No	N/A		1 765		N/A	
Irrigation Solutions Used in Pocket		0.9918		0.1419		0.8891
Saline Only	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Steroid Only	>100		N/A		N/A	
Antibiotic Only	>100		0.047		0.462	
Drug Only	>100		0.000		0.354	
Other	>100		0.173		0.777	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.8

EXPLANTATION (REMOVAL) FOR ANY REASON WITHOUT REPLACEMENT· COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.6632		0.2758		0.3116
<=349 cc	N/A		N/A		N/A	
350-399 cc	1.926		3.940		6.389	
400-499 cc	1.400		3.506		3.285	
500-599 cc	6.966		4.970		8.349	
>=600 cc	0.350		12.784		0.956	
Site		1.0000		0.9574		0.3599
Pooled Site	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Site 1	3.519					
Site 2	1.341		N/A		0.000	
Site 3	0.000		N/A		N/A	
Site 4	0.000		N/A		N/A	
Site 5	0.000		N/A		N/A	
Site 7	1.836		N/A		N/A	
Site 8	0.139		N/A		N/A	
Site 10	0.000		N/A		5.623	
Site 12	0.000		N/A		N/A	
Site 13	0.000		N/A		N/A	
Site 15	0.619		N/A		N/A	
Site 18	1.062		N/A		N/A	
Site 19	N/A		2.071		5.013	
Site 23	>100		N/A		N/A	
Site 30	N/A		0.000		N/A	
Site 33	N/A		0.324		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.8

EXPLANTATION (REMOVAL) FOR ANY REASON WITHOUT REPLACEMENT: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 48	N/A		0.000		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08.58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.9

ANY REOPERATION TO THE BREAST OR SURROUNDING AREAS. COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	1.006	0.6840	1.064	0.0002	0.993	0.6792
Race		0.5574		0.7213		0.3914
Caucasian	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Other	0.793		1.193		1.653	
Smoking Status		0.3096		0.0105		0.8462
No	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Yes	0.715		0.066		0.926	
Surgical Approach		0.0042		0.8673		0.4169
Inframammary	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Periareoloar	0.566		0.753		0.589	
Transaxillary	1.056		N/A		0.000	
Mastectomy Scar	N/A		0.792		0.611	
Other/Mixed	5.181		1.117		1.723	
Surgical Placement		0.1673		0.0167		0.5664
Submuscular	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Subglandular	1.731		2.569		0.857	
Subpectoral	2.296		0.554		0.450	
Other/Mixed	N/A		3.412		0.000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.9

ANY REOPERATION TO THE BREAST OR SURROUNDING AREAS: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	0.952	0 5736	0.933	0.2222	1.091	0.1671
Surface Type						
Smooth	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Textured	1.000		0.893		0.564	
Mixed	N/A		N/A		N/A	
Prior Tissue Expander*				0.6739		
Yes			1.000 (reference)			
No	N/A		0.810		N/A	
Irrigation Solutions Used in Pocket		0.1631		0 7025		0.9396
Saline Only	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Steroid Only	0.000		N/A		N/A	
Antibiotic Only	0.630		1.264		0.762	
Drug Only	7.746		3.399		0.000	
Other	2.739		1.425		0.859	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.9

ANY REOPERATION TO THE BREAST OR SURROUNDING AREAS: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.8408		0.0073		0.8356
<=349 cc	N/A		N/A		N/A	
350-399 cc	0.820		2.325		1.259	
400-499 cc	0.775		0.555		1.333	
500-599 cc	1.360		2.878		1.059	
>=600 cc	0.000		3.185		0.714	
Site		0.3928		0.3184		0.3404
Pooled Site	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Site 1	1.572					
Site 2	0.358		N/A		1.345	
Site 3	0.646		N/A		N/A	
Site 4	0.900		N/A		N/A	
Site 5	1.298		N/A		N/A	
Site 7	0.258		N/A		N/A	
Site 8	0.304		N/A		N/A	
Site 10	0.244		N/A		2.448	
Site 12	0.210		N/A		N/A	
Site 13	0.397		N/A		N/A	
Site 15	0.647		N/A		N/A	
Site 18	0.299		N/A		N/A	
Site 19	N/A		1.490		1.927	
Site 23	0.196		N/A		N/A	
Site 30	N/A		0.000		N/A	
Site 33	N/A		1.596		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note. Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.9

ANY REOPERATION TO THE BREAST OR SURROUNDING AREAS: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 48	N/A		0.257		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note. Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.10

ANY COMPLICATION, COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Age (years)	1.002	0.8550	1.002	0.8383	0.975	0.0503
Race		0.0930		0.9478		0.7122
Caucasian	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Other	1.449		0.975		0.830	
Smoking Status		0.4977		0.8329		0.1554
No	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Yes	0.872		0.920		0.619	
Surgical Approach		0.0983		0.9962		0.7152
Inframammary	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Periareoloar	0.675		1.020		0.966	
Transaxillary	1.051		N/A		0.000	
Mastectomy Scar	N/A		1.089		1.584	
Other/Mixed	2.451		1.051		1.467	
Surgical Placement		0.8097		0.7842		0.6043
Submuscular	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Subglandular	0.996		0.980		1.220	
Subpectoral	0.852		1.307		1.527	
Other/Mixed	N/A		1.597		0.000	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.10

ANY COMPLICATION: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.011	0.8623	0.945	0.1745	1.084	0.1015
Surface Type						
Smooth	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Textured	1.484		1.035		0.875	
Mixed	N/A		N/A		N/A	
Prior Tissue Expander*				0.5757		
Yes			1.000 (reference)			
No	N/A		0.824		N/A	
Irrigation Solutions Used in Pocket		0.9155		0.8066		0.1069
Saline Only	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Steroid Only	2.478		N/A		N/A	
Antibiotic Only	1.233		0.972		0.454	
Drug Only	1.172		1.741		0.000	
Other	1.442		0.785		0.580	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08.58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.10

ANY COMPLICATION: COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Implant Size		0.5294		0.9566		0.5102
<=349 cc	N/A		N/A		N/A	
350-399 cc	0.766		1.006		0.911	
400-499 cc	0.825		0.822		0.958	
500-599 cc	1.298		0.965		0.980	
>=600 cc	0.768		1.158		0.422	
Site		0.9379		0.3666		0.0013
Pooled Site	1.000 (reference)		1.000 (reference)		1.000 (reference)	
Site 1	1.169					
Site 2	0.976		N/A		3.881	
Site 3	0.674		N/A		N/A	
Site 4	0.776		N/A		N/A	
Site 5	1.172		N/A		N/A	
Site 7	0.596		N/A		N/A	
Site 8	1.458		N/A		N/A	
Site 10	0.705		N/A		4.149	
Site 12	0.460		N/A		N/A	
Site 13	1.116		N/A		N/A	
Site 15	0.875		N/A		N/A	
Site 18	0.762		N/A		N/A	
Site 19	N/A		1.196		1.821	
Site 23	0.778		N/A		N/A	
Site 30	N/A		0.427		N/A	
Site 33	N/A		1.431		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note. Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not.associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.10

ANY COMPLICATION. COX REGRESSION

	Augmentation Patients		Reconstruction Patients		Revision Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value	Estimated Hazard Ratio	p-value
Site 48	N/A		0.631		N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1.A

INFECTION. COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Age (years)	0.899	0.0565
Race		0.9965
Caucasian	1.000 (reference)	
Other	0.000	
Smoking Status		0.2944
No	1.000 (reference)	
Yes	0.263	
Surgical Approach		0.4471
Inframammary	1.000 (reference)	
Periareoloar	12.986	
Transaxillary	0.000	
Mastectomy Scar	N/A	
Other/Mixed	0.000	
Surgical Placement		0.2226
Submuscular/Subpectoral	1 000 (reference)	
Subglandular	3.897	
Other/Mixed	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note. Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1.A

INFECTION. COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.493	0.2914
Surface Type		
Smooth	1.000 (reference)	
Textured	0.283	
Mixed	N/A	
Prior Tissue Expander*		
Yes		
No	N/A	
Irrigation Solutions Used in Pocket		0.7184
Saline Only	1.000 (reference)	
Steroid Only	>100	
Antibiotic Only	13.705	
Drug Only	>100	
Other	1.936	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note. Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1.A

INFECTION: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Implant Size		0.4369
<=349 cc	N/A	
350-399 cc	7.572	
400-499 cc	14.774	
500-599 cc	10.012	
>=600 cc	0.000	
Site		0.9841
Pooled Site	1.000 (reference)	
Site 1	0.000	
Site 2	0.000	
Site 3	0.000	
Site 4	>100	
Site 5	0.000	
Site 7	7.256	
Site 8	0.000	
Site 10	0.216	
Site 12	0.000	
Site 13	0.000	
Site 15	0.044	
Site 18	0.000	
Site 19	N/A	
Site 23	0.000	
Site 30	N/A	
Site 33	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.1.A

INFECTION: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Site 48	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note. Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2.A

RUPTURE: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Age (years)		**
Race		
Caucasian		
Other		
Smoking Status		
No		
Yes		
Surgical Approach		
Inframammary		
Periareoloar		
Transaxillary		
Mastectomy Scar		
Other/Mixed		
Surgical Placement		
Submuscular/Subpectoral		
Subglandular		
Other/Mixed		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 27AUG04 11:59

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Too Few patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2.A

RUPTURE: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Incision Size (cm)		
Surface Type		
Smooth		
Textured		
Mixed		
Prior Tissue Expander*		
Yes		
No		
Irrigation Solutions Used in Pocket		
Saline Only		
Steroid Only		
Antibiotic Only		
Drug Only		
Other		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 27AUG04 11:59
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Too Few patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2.A

RUPTURE: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Implant Size		
<=349 cc		
350-399 cc		
400-499 cc		
500-599 cc		
>=600 cc		
Site		
Pooled Site		
Site 1		
Site 2		
Site 3		
Site 4		
Site 5		
Site 7		
Site 8		
Site 10		
Site 12		
Site 13		
Site 15		
Site 18		
Site 19		
Site 23		
Site 30		
Site 33		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 27AUG04 11:59

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Too Few patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.2.A

RUPTURE: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Site 48		

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 27AUG04 11.59

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Too Few patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.3.A

CAPSULAR CONTRACTURE GRADE III, OR IV: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Age (years)	1.021	0.2771
Race		0.7611
Caucasian	1.000 (reference)	
Other	0.855	
Smoking Status		0.6924
No	1.000 (reference)	
Yes	1.175	
Surgical Approach		0 5411
Inframammary	1.000 (reference)	
Periareoloar	1.062	
Transaxillary	0.906	
Mastectomy Scar	N/A	
Other/Mixed	3.119	
Surgical Placement		0.0693
Submuscular/Subpectoral	1.000 (reference)	
Subglandular	2.064	
Other/Mixed	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.3.A

CAPSULAR CONTRACTURE GRADE III, OR IV: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Incision Size (cm)	0.958	0.6957
Surface Type		
Smooth	1.000 (reference)	
Textured	0.000	
Mixed	N/A	
Prior Tissue Expander*		
Yes		
No	N/A	
Irrigation Solutions Used in Pocket		0.1432
Saline Only	1.000 (reference)	
Steroid Only	28.968	
Antibiotic Only	1.524	
Drug Only	14.021	
Other	7.067	

Program Name: Q.\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.3.A

CAPSULAR CONTRACTURE GRADE III, OR IV: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Implant Size		0.8017
<=349 cc	N/A	
350-399 cc	0.828	
400-499 cc	0.599	
500-599 cc	1.117	
>=600 cc	0.000	
Site		0.7412
Pooled Site	1.000 (reference)	
Site 1	>100	
Site 2	0.992	
Site 3	0.762	
Site 4	>100	
Site 5	0.883	
Site 7	0.000	
Site 8	>100	
Site 10	0.177	
Site 12	0.000	
Site 13	0.000	
Site 15	0.670	
Site 18	0.418	
Site 19	N/A	
Site 23	0.182	
Site 30	N/A	
Site 33	N/A	
Site 48	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4.A

NIPPLE SENSATION CHANGES: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Age (years)	1.010	0.6173
Race		0.3545
Caucasian	1.000 (reference)	
Other	1.431	
Smoking Status		0.2368
No	1.000 (reference)	
Yes	0.612	
Surgical Approach		0.6972
Inframammary	1.000 (reference)	
Periareoloar	0.834	
Transaxillary	0.255	
Mastectomy Scar	N/A	
Other/Mixed	0.701	
Surgical Placement		0.5488
Submuscular/Subpectoral	1.000 (reference)	
Subglandular	1.244	
Other/Mixed	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4.A

NIPPLE SENSATION CHANGES. COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.171	0.0834
Surface Type		
Smooth	1.000 (reference)	
Textured	1.167	
Mixed	N/A	
Prior Tissue Expander*		
Yes		
No	N/A	
Irrigation Solutions Used in Pocket		0.6554
Saline Only	1.000 (reference)	
Steroid Only	0.000	
Antibiotic Only	2.427	
Drug Only	2.488	
Other	1.495	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4.A

NIPPLE SENSATION CHANGES: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Implant Size		0.2813
<=349 cc	N/A	
350-399 cc	0.754	
400-499 cc	0.470	
500-599 cc	1.881	
>=600 cc	0.000	
Site		0.5104
Pooled Site	1.000 (reference)	
Site 1	1.868	
Site 2	1.520	
Site 3	0.244	
Site 4	0.375	
Site 5	0.186	
Site 7	0.341	
Site 8	2.416	
Site 10	0.212	
Site 12	0.839	
Site 13	1.815	
Site 15	0.823	
Site 18	0.978	
Site 19	N/A	
Site 23	0.866	
Site 30	N/A	
Site 33	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.4.A

NIPPLE SENSATION CHANGES. COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Site 48	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time. 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.5.A

BREAST SENSATION CHANGES· COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Age (years)	0.984	0.7269
Race		0.2660
Caucasian	1.000 (reference)	
Other	2.678	
Smoking Status		0.8438
No	1.000 (reference)	
Yes	0.837	
Surgical Approach		0.9767
Inframammary	1.000 (reference)	
Periareoloar	0.583	
Transaxillary	0.000	
Mastectomy Scar	N/A	
Other/Mixed	0.000	
Surgical Placement		0.8624
Submuscular/Subpectoral	1.000 (reference)	
Subglandular	0.852	
Other/Mixed	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58

* Only Included in model for Reconstruction Patients.

Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.

** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10 5.A

BREAST SENSATION CHANGES: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Incision Size (cm)	1.108	0.5872
Surface Type		
Smooth	1.000 (reference)	
Textured	0.514	
Mixed	N/A	
Prior Tissue Expander*		
Yes		
No	N/A	
Irrigation Solutions Used in Pocket		0.3699
Saline Only	1.000 (reference)	
Steroid Only	>100	
Antibiotic Only	>100	
Drug Only	>100	
Other	>100	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.5.A

BREAST SENSATION CHANGES: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Implant Size		0.7245
<=349 cc	N/A	
350-399 cc	0.203	
400-499 cc	0.782	
500-599 cc	0.000	
>=600 cc	0.058	
Site		0.9514
Pooled Site	1.000 (reference)	
Site 1	0.000	
Site 2	34.556	
Site 3	0.000	
Site 4	0.609	
Site 5	0.580	
Site 7	0.000	
Site 8	>100	
Site 10	0.000	
Site 12	0.000	
Site 13	29.005	
Site 15	9.217	
Site 18	0.000	
Site 19	N/A	
Site 23	9.923	
Site 30	N/A	
Site 33	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08:58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following: asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
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Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 10.5.A

BREAST SENSATION CHANGES: COX REGRESSION

	Augmentation Patients	
Explanatory Variables	Estimated Hazard Ratio	p-value
Site 48	N/A	

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T10_A.SAS Creation Date, Time: 24AUG04 08 58
* Only Included in model for Reconstruction Patients.
Note: Excludes planned second stage surgeries and mild occurrences of the following. asymmetry, breast pain not associated with any other complication, calcification, position change, nipple-unacceptably low sensitivity, breast-unacceptably low/high sensitivity, nipple complications, and wrinkling.
** Fewer than 5 patients reported the event. Consequently no analyses were performed.